DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, Maryland 21244

Date: January 24, 2005

To: Presidents/Chief Executive Officers of Medicare Advantage Organizations, Cost-based Plans, and Preferred Provider Organization Demonstrations

From: Patricia Smith, Director, Medicare Advantage Group
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Subject: Guidance for Medicare Advantage (MA) (formerly Medicare+Choice (M+C)) Organizations, 1876 Cost-based Plans, and Preferred Provider Organization (PPO) demonstrations regarding how to comply with transition requirements established in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)

This communication is directed to current Medicare contractors – specifically MA/M+C organizations, PPO demonstrations – that intend to transition to the expanded Medicare Advantage program in January 2006; and Cost-based Plans. This memo provides an overview of the steps that health plans must take to be compliant with MMA as of January 1, 2006. Specific to Cost-based Plans, this MMA transition guidance provides information and instructions for Cost-based Plans that are choosing to offer a Part D benefit.

This guidance is part of CMS' ongoing effort to provide the health plan industry with information about how to comply with the 2006 MMA requirements. Please note that the guidance in this memo also applies both to current contractors and to all health plan organizations that anticipate having a contract either approved or effective with CMS prior to January 1, 2006. In addition to this memo, CMS will provide more detailed information after the final regulation is published, including the 2006 Call Letter for health plans. The CMS health plan website (http://www.cms.hhs.gov/healthplans/) is updated regularly and now includes a link to the Key Projected Dates in the implementation of Title I and Title II (http://www.cms.hhs.gov/medicarereform/mma-t1t2-calendar.pdf)that is also updated regularly. We encourage you to check these sources routinely for up-to-date information regarding the MMA transition requirements.

Background

The MMA will expand and reform the availability of private health plan choices for Medicare beneficiaries while retaining most key features of the pre-MMA M+C program. The new law enriches the Medicare Program by adding a prescription drug benefit for beneficiaries and

adding a new option, Regional PPOs, to the list of plan types available in Medicare. The MMA also builds on the care coordination that already exists in Medicare managed care by adding special needs plans (SNPs) that are designed to better serve the needs of dually eligible and institutional beneficiaries and those with complex and disabling diseases and conditions.

Statutory and Regulatory References

The President signed the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub.L.108-173) on December 8, 2003. The final implementing regulations were published on January 21, 2005. The final MA regulations are codified in 42 CFR 422.

Effective Dates of New Rules

The Final Regulations generally will be effective 60 days after publication, with some provisions expected to be effective later as specified. As is the case with the major changes made by MMA, most major changes in the final rule apply to the contract year beginning January 1, 2006. Because the 2006 contracts are dependent on actions during 2005, the timeframes below set out the actions that must occur before January 1, 2006.

Information To Be Submitted By Transitioning Organizations

In order to transition to a 2006 contract under the new rules or to comply with new requirements in the Title I and Title II final regulations, MA organizations, 1876 Cost-based Plans, and PPO demonstrations must submit information to CMS according to the following timelines.

1. A signed MA/Cost-based Plan Transition Attestation, due by March 23, 2005. This attestation indicates an organization's intent to renew its contract with CMS and transition to 2006 requirements that are applicable to their organization. A submission of a signed attestation enables CMS to have assurances that the organization is fully aware of the MA 2006 requirements and that it is in compliance. A signed attestation is a substitution for submission of detailed compliance information. Compliance with these 2006 requirements is subject to CMS verification at a later date.

   Note: Signing the attestation does not prevent an MA organization or Cost-based Plan from non-renewing. It should also be submitted by an organization that has an application in process and expects to be approved for the 2005 contract year. It also does not impact whether a PFFS, or Cost-based Plan will offer a Part D option.

   Additionally, the return of the attestation will allow CMS to set up the mechanisms and automated systems to transition organizations, accept a Prescription Drug (PD) application, and process the MA bid.

2. Business Integrity - An attestation as to the organization's involvement over the past three years in any investigations, legal actions or arbitrations brought by a state or federal government agency relating to payments for healthcare and/or prescription drug services. CMS will provide the attestation shortly.

3. A Prescription Drug Benefit application, if applicable, by March 23, 2005; and

4. An MA-PD bid submission by June 6, 2005. Bid forms are posted at http://www.cms.hhs.gov/medicarereform. MA PBP screenshots are available at http://www.cms.hhs.gov/healthplans/applications/ while the Part D PBP screenshots are available at http://www.cms.hhs.gov/pdps/.

The following enclosures provide additional guidance and detail about the required pieces of information, including guidance specific to the phase out of the Medicare PPO Demonstration (Enclosure B). Guidance for other organizations that offer other MA demonstration products such as Social Health Maintenance Organizations (SHMOs) will be communicated separately. Please note that requirements specific to the Program of All Inclusive Care for the Elderly (PACE) are available at http://www.cms.hhs.gov/pace .

Enclosure A. Medicare Advantage Transition Requirements is a summary listing the significant MA requirements that first apply to the 2006 contract year. The enclosure provides instructions and guidance about the information that must be submitted to CMS. The requirements discussed are: (1) Quality Improvement (QI), (2) bid submission, and (3) the Part D MA-PD application. In addition, there is a brief description of how various types of health plans are affected by the Part D requirements, that is, whether the Part D application must be provided as part of the transition.

Enclosure B. Requirements for PPO Demonstrations to Transition to Non-demonstration MA Contracts provides special guidance for the PPO Demonstration products which end on December 31, 2005.

Enclosure C. Attestation of Compliance for Part C and Part D Requirements or Exemptions From Such Requirements is an attestation form that must be signed by any MA organization (MAO) or Cost-based Plan intending to participate in Medicare Part C and Part D in 2006. It is also an attestation that identifies plans in the following categories that are exempt or not subject to specified requirements:

(1) Medical Savings Accounts - exempt from the QI requirement at 42 CFR 422 Subpart D and are not allowed to offer Part D drug coverage.

(2) Private-Fee-For-Service plans - exempt from the QI requirement at 42 CFR 422 Subpart D and have an option to offer the Part D drug coverage.

(3) Cost-based plans – not subject to the QI requirements at 42 CFR 422 Subpart D and have an option to offer the Part D drug coverage.

Enclosure D. Business Integrity Attestation is an attestation form that must be signed by any MA organization (MAO) or Cost-based Plan intending to participate in Medicare Part C in 2006. Entities that cannot attest to this must submit a brief explanation of any of the described occurrences pursuant to the instructions on the attestation. CMS will provide the attestation shortly.

Who Must Submit Information

All current MA contractors, 1876 Cost-based Plans, and PPO demonstrations must submit the attestation as the first step in the transition to the post-2005 MA rules. Additional instructions may be necessary following the publication of the Final Regulation, including those for other demonstration projects, will be forthcoming shortly.

The Transition Process

CMS will review and process the attestation indicated above, a Part D application, a bid and any other information CMS needs to determine if the transitional plan is complete and acceptable. Approved transitional plans will be awarded contracts during September 2005 for 2006.

Health Plan Management System (HPMS) Contact Information

To ensure a smooth transition to the 2006 rules, we urge health plans to update and maintain current health plan contact information in the CMS HPMS. CMS will communicate via HPMS and e-mail to the health plan's Medicare compliance contact listed in HPMS. All CMS communications about the MA/M+C, Cost-based Plan and PPO demonstration transitions will use the contact information that health plans provide in HPMS. The following information must be up to date: name of MA organization, Medicare compliance contact, mailing address, E-mail address, telephone number, and fax number. **Please update this information, as soon as possible, but no later than March 10, 2005.**

In addition, CMS strongly recommends that all organizations update the HPMS information at least quarterly in order to ensure timely receipt of CMS communications. Additional information concerning HPMS may be found at http://32.91.239.68/hpms/secure/home.asp. If you have problems entering this information into HPMS, please contact the HPMS Help Desk at 1-800-220-2028.

Where to Send Information

Please send signed attestations to:

Centers for Medicare & Medicaid Services
Attn: MMA Transition – Alisa Stapleton
Media Center
CMS
7500 Security Boulevard
Baltimore, MD 21244

Please refer to the references below for information on where to send the Part D application and bid submission materials.

Additional References

Please refer to the following web sites for additional information on the 2006 MA transition and requirements. Each web site provides E-mail addresses for submitting questions or comments.

MA Health Plan information – http://www.cms.hhs.gov/healthplans.

Medicare 2006 Application Materials – http://www.cms.hhs.gov/healthplans.

Up-To-Date Calendar for MA Organizations – http://www.cms.hhs.gov/healthplans/letters/ and http://www.cms.hhs.gov/medicarereform.

Prescription Drug Plan Information – http://www.cms.hhs.gov/pdps.

CMS is committed to working with all our current contractors to ensure a smooth transition to the MA program for our beneficiaries. If the above web sites cannot address your questions or concerns, please contact Danielle Harris at 410-786-1819 and she will refer you to the proper person.

Enclosure A

Medicare Advantage (MA) (formerly Medicare+Choice) and 1876 Cost-Based Plan Transition Requirements

This summary is for organizations with a Medicare contract prior to 2006 and is not intended for new organizational types such as Regional PPOs. The following is a list of major new MA requirements that will apply to the 2006 contract year with instructions on what information needs to be submitted to CMS for transition to 2006.

1. Quality Improvement (QI) – MA organizations are required to operate a Chronic Care Improvement Program. MA organizations must develop criteria and/or methods for identifying MA enrollees with multiple chronic conditions who would benefit from participating in chronic care improvement activities. MA organizations then must monitor the care of enrollees in such program. Also, MA organizations must operate a QI program and measure performance, system interventions, performance improvement and periodic follow-up. MA organizations will be required to report these QI activities to CMS. (Note that several current requirements are deleted effective 2006, including plan participation in a national or site-wide project and the prescribed list of clinical and non-clinical topic areas for projects.)

Certain MA plan types will have different requirements under QI. For example, Private Fee-for-Service (PFFS) plans are excluded from QI requirements, and PPOs are only required to collect, analyze and report quality data on providers under contract with the PPO.

Transition Instructions: CMS is not requiring MA organizations to submit information on the QI requirements. MA organizations are only required to sign the attestation (Enclosure C) attesting to meeting all QI requirements in 42 CFR 422 Subpart D by January 1, 2006.

2. Submission of Bids – Organizations transitioning to post-2005 MA program will now use a bidding process under which each organization's basic bid for providing services covered under Part A and Part B will be compared to "benchmark" amounts established by statute. On the first Monday of June, beginning in 2005, MA organizations must submit a bid for each MA plan they intend to offer the upcoming year based on their determination of the plan's monthly expected revenue needs. Bids must also reflect enrollee cost-sharing that is actuarially equivalent to that imposed under the original Medicare fee-for-service program. If this amount is higher than the benchmark amount, this amount must be charged as a premium for Parts A and B benefits. If the bid amount is lower, 75 percent of the difference must be offered to enrollees in benefits or rebates, with the remaining 25 percent reverting to the Medicare trust funds. Each bid will have three components, original Medicare benefits (Parts A/B), basic prescription drug coverage under Part D (if any), and supplemental benefits (if any). CMS will review bids and may request additional information. CMS has not determined the precise format of the bid submission at this time and will be announcing these specifications after publication of the final MA regulations.

3. Requirement to offer Medicare Advantage-Prescription Drug (MA-PD) Plan-
Under the MMA, MA organizations offering a coordinated care plan must offer at least one MA plan throughout that plan's service area that includes prescription drug coverage under Part D. These MA organizations must apply for qualification to offer a Part D plan. The Part D portion of the MA transition application is also referred to as the "MA-PD application."

The MA-PD application must be submitted by March 23, 2005. Instructions for completing the MA-PD application will be provided in the application. The MA-PD application will be posted on the CMS website in late January, 2005. Current MA sponsors can expect the MA-PD application to be an abbreviated version of the Part D application for PDPs, reflecting the waivers CMS will automatically apply to certain PDP requirements as discussed below. Requirements for specific types of contractors are as follows:

- MA organizations offering one or more Coordinated Care Plans must offer at least one plan throughout their service are of each such plan that includes prescription drug coverage under Part D and therefore must complete the MA-PD application and submit a successful bid.

- A PFFS Plan may offer prescription drug coverage under Part D at their option.

- Regional PPO Plan Contractors must offer at least one plan throughout their service areas that includes prescription drug coverage under Part D and therefore must complete the MA-PDP application and submit a successful bid.

- To receive payment transitioning PACE organizations must offer Part D coverage to Part D-eligible enrollees. Further guidance is forthcoming on the process for approval of Part D benefits for PACE organizations.

- Medical Savings Account Plans may not offer prescription drug coverage under Part D.

- Medicare Cost-based Contractors that choose to offer Part D benefits must offer a qualified prescription drug plan. Cost-based Contractors that offer Part D benefits must complete the MA-PD application and submit a successful bid.

<u>Waivers from Prescription Drug Plan (PDP) requirements</u>.

The MA-PD and Cost-based Plan Prescription Drug applications identify those PDP sponsor requirements that CMS will waive for MA-PD and Cost Plan Applicants because the requirements; 1) either conflict with or duplicate MA or Cost Plan requirements or; 2) the waivers will help to promote the coordination of Part C and Part D benefits by the MA-PD sponsor or the coordination of benefits offered by Cost-based Plans and benefits under Part D. Waivers will not be granted where they would have the effect of compromising the value of the drug benefit contemplated under MMA.

CMS will be granting waivers on its own initiative of the specific requirements listed in an appendix of the MA-PD and Cost Plan Part D solicitations. In addition to these waivers, MA-PD

and Cost Plan Applicants will to able to make requests for waivers at the time of application using the same coordination of benefits or conflicting/duplicative requirements justifications. Once approved by CMS, these waivers will be applicable to every similarly situated MA-PD sponsor. All of the approved waivers (both CMS and Applicant-initiated) will be reflected in a Part D amendment to the MA contract.

CMS will provide additional information regarding the submission of these transitions elements in late winter/early spring.

NOTE: Information on employer waivers for Part C and Part D will be issued in sub-regulatory guidance early in 2005

Enclosure B

Requirements for PPO Demonstrations to Transition to Non-demonstration MA Contracts

Section 221(a)(2) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) provides a moratorium on new local PPO plans in contract years 2006 and 2007. The MMA states the following: "The Secretary shall not permit the offering of a local PPO plan under Part C of Title XVIII of the Social Security Act during 2006 or 2007 in a service area unless such plan (including a demonstration project under such part) was offered in such service area as of December 31, 2005." Therefore, PPO Demonstration organizations may provide local PPO products in contract years 2006 and 2007 under the Medicare Advantage program after the demonstration terminates on December 31, 2005.

In order for PPO demonstrations to transition to non-demonstration Medicare Advantage (MA) contracts offering a local PPO plan in 2006, the same transition requirements noted for all other M+C and/or MA organizations in this document must be met. In addition, please note the following information:

Service Area Expansion of the PPO Demonstration in 2005 – Service area expansions of PPO demonstrations will be allowed as long as the proposed expanded area is in the same State, or in contiguous counties in an adjacent State, and there are no licensure issues that would prevent the expansion to the adjacent State. Service area expansion applications must be submitted by March 1, 2005 (MLR/PBP required). All requirements must be met by June 1, 2005 and the effective date of the SAE can be no later than September 1, 2005.

Submittal of Application to Transition to 2006 MA program (when/if needed) – Submittal of new applications will not be required for PPO demonstrations to transition to the regular MA program offering a local PPO plan in 2006, except in cases where the organization must apply as a new and/or different State-licensed entity. New H (contract) numbers for 2006, however, will be issued to all transitioning PPO demonstrations. The old H number under the demonstration will be used for tracking purposes related to demonstration payments, reconciliation, waivers, etc. There will be a final reconciliation of the demonstration H# that is no longer active.

If a new application is required (in cases where the organization must apply as a new and/or different State-licensed entity in order to offer a local PPO plan), we will typically only request an abbreviated application since virtually all of the organizations participating in the demonstration have extensive experience with Medicare contracting. The abbreviated application requirements will be determined on a case-by-case basis. The CO Plan Manager should be contacted concerning further information in this regard. However, the mandatory minimal items currently required include (1) the application cover sheet, (2) the summary description, (3) the ACRP, (4) the service area description, and (5) authority to operate in the State with appropriate licensure to offer a PPO plan. The application needs to be submitted by March 23, 2005, all requirements must be met by June 1 and the effective date can be no later than September 1, 2005. Note: PPO demonstrations that wish to participate as a Regional PPO

must complete the Regional PPO application and should carefully review the timeline and guidance provided by CMS for these applications.

Covered Services of PPO plans – PPO demonstrations offering local MA PPO plans in 2006 must provide all covered benefits in or out-of-network, including all Medicare Part A & B benefits, as well as any additional/ supplemental benefits offered. Additional guidance regarding prior authorization rules, as it relates to local MA PPO plans, will be provided in the 2006 Call Letter.

Enrollment/Plan Notifications – CMS will work with each organization to determine the enrollment and plan notification requirements necessary to make the PPO demonstration transition smooth for the Medicare beneficiaries and to ensure their rights are protected.

Execution of new MA Contract in 2006 – PPO demonstrations that will transition to MA contracts offering a local PPO plan will be required to sign new MA contracts effective January 1, 2006, along with all other current MA organizations.

Enclosure C

Attestation of Compliance for Medicare Part C and Part D Requirements or Exemption From Such Requirements

Part C
By signing this attestation, the Medicare Advantage Organization agrees that it will meet all requirements at Section 1852 of the Social Security Act (the Act), 42 CFR 422, Subpart D, Quality Improvement by January 1, 2006.

Part D
I understand that Section 1860-21 of the Act may require my organization to offer Medicare Part D benefits under 42 CFR 423. Further, I understand that should my organization be required to offer Part D benefits, or if my organization voluntarily offers to provide Part D benefits, the Medicare Advantage-Prescription Drug application (or in the case of a Cost-based Plan, the Cost Plan Part D application) and Part D bid must be approved.

Cost-based Plans
Requirements for Cost-based Plans are at Section 1876 of the Social Security Act and are subject to regulations at 42 CFR Part 417. Title I legislation provides Cost-based Plans with the option of providing Medicare Part D benefits.

I agree that CMS may inspect any and all information necessary including inspections at the premises of the Medicare Advantage Organization or Plan to ensure compliance with stated Federal requirements including specific provisions for which I have attested. I further agree to immediately notify CMS if despite this attestation, I become aware of circumstances which preclude full compliance by January 1, 2006 with the requirements indicated above.

Name of Organization: _____

Printed Name of CEO: _____ Signature: _____

Medicare Advantage Contract Numbers:
H#"s _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

___ Place an "X" here and sign above if your organization is not offering a Part D drug benefit. Also, indicate if you are one of the following:

PFFS H#____ H# ____ Cost-based Plan H#____ H#____ MSA H#____ H#____

NOTES:

- **This attestation form must be signed by any MA organization or Cost Plan that intends to continue contracting with CMS in January 1, 2006.**
- **MSAs are not allowed to offer the Part D benefit and they are exempt from Quality Improvement regulation at 42 CFR 422 Subpart D.**

- **PFFS Plans have an option to provide the Part D drug benefit and they are exempt from the Quality Improvement regulation at 42 CFR 422 Subpart D.**
- **Cost-based Plans have an option to provide the Part D drug benefit and are not subject to 42 CFR 422 Subpart D.**
- Signing this attestation does not prevent any organization from non-renewing with CMS or from offering the Part D benefit if it is an option.